PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 124.554, the Board of Pharmacy and the Prescription Monitoring Program Advisory Council hereby give Notice of Intended Action to amend Chapter 24, "Pharmacy Internet Sites," and Chapter 37, "Iowa Prescription Monitoring Program," Iowa Administrative Code.

The amendments were approved at the January 19, 2012, regular meeting of the Board of Pharmacy. The amendments were approved by the Prescription Monitoring Program Advisory Council by electronic communications between February 27, 2012, and March 5, 2012.

The proposed amendments:

- Change the definition of "dispenser" to include nonresident pharmacies that dispense prescriptions for controlled substances in Schedules II through IV of Iowa Code chapter 124;
- Amend the requirement for reporting of those substances, contained in Chapter 24 regarding pharmacy Internet sites, to ensure that all pharmacies dispensing Schedules II through IV controlled substances to patients located in Iowa understand the requirement for reporting those prescriptions to the Iowa Prescription Monitoring Program (PMP);
- Identify those pharmacies that may be exempt from reporting to the Iowa PMP and establish processes for claiming such exemption; and
- Change prescription reporting frequency from twice monthly to weekly reporting and establish a timely reporting deadline.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on June 5, 2012. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code section 124.552.

The following amendments are proposed.

ITEM 1. Amend subrule 24.3(3) as follows:

24.3(3) *Iowa PMP.* A pharmacy, wherever located, within Iowa that provides any controlled substance included in Schedules II through IV of Iowa Code chapter 124 to any patient within Iowa, unless the pharmacy is exempt from reporting pursuant to 657—subrule 37.3(1), shall report those dispensed prescriptions to the Iowa PMP as provided in rule 657—37.3(124).

ITEM 2. Amend rule **657—37.2(124)**, definition of "Dispenser," as follows:

"Dispenser" means a person who delivers to the ultimate user a substance required to be reported to the PMP database. "Dispenser" includes a pharmacy located outside the state of Iowa that is licensed by the board with a nonresident pharmacy license authorizing the pharmacy to dispense prescription drugs to patients in Iowa. "Dispenser" does not include a person exempt from reporting pursuant to subrule 37.3(1).

ITEM 3. Amend rule 657—37.3(124) as follows:

- **657—37.3(124) Requirements for the PMP.** Each dispenser, unless identified as exempt from reporting pursuant to subrule 37.3(1), shall submit to the PMP administrator a record of each reportable prescription dispensed during a reporting period. A dispenser located outside the state of Iowa, unless identified as exempt from reporting pursuant to subrule 37.3(1), shall submit to the PMP administrator a record of each reportable prescription dispensed during a reporting period to a patient located in Iowa.
- **37.3(1)** *Exemptions.* The dispensing of a controlled substance as described in this subrule shall not be considered a reportable prescription. A dispenser engaged in the distribution of controlled substances solely pursuant to one or more of the practices identified in paragraphs 37.3(1) "a" or 37.3(1) "b" of this subrule shall so notify the PMP administrator and shall be exempt from reporting to the PMP.
- a. A licensed hospital pharmacy shall not be required to report the dispensing of a controlled substance for the purposes of inpatient hospital care, the dispensing of a prescription for a starter supply of a controlled substance at the time of a patient's discharge from such a facility, or the dispensing of a prescription for a controlled substance in a quantity adequate to treat the patient for a maximum of 72 hours. A hospital pharmacy claiming exemption from reporting pursuant to this paragraph shall certify to the board that the hospital pharmacy dispenses only as provided by this paragraph.
- b. A licensed pharmacy shall not be required to report the dispensing of a controlled substance for a patient residing in a long-term care facility or for a patient residing in an inpatient hospice facility. A pharmacy claiming exemption from reporting pursuant to this paragraph shall certify to the board that the pharmacy dispenses only to patients residing in a long-term care facility or to patients residing in an inpatient hospice facility.
 - c. and d. No change.
 - **37.3(2)** No change.
- **37.3(3)** Reporting periods. A record of each reportable prescription dispensed shall be submitted by each dispenser pursuant to the following schedule at least weekly. Records may be submitted with greater frequency than required by this schedule. This schedule defines minimum report frequency subrule. Records of reportable prescriptions dispensed between Sunday and Saturday each week shall be submitted no later than the following Wednesday.
- a. Records of reportable prescriptions dispensed between the first and the fifteenth day of a month shall be submitted no later than the twenty-fifth day of the month.
- b. Records of reportable prescriptions dispensed between the sixteenth and the last day of a month shall be submitted no later than the tenth day of the following month.
 - 37.3(4) and 37.3(5) No change.